

THE WAY FORWARD

OUT OF THE CHEMICALS CRISIS

**AN ALTERNATIVE, PRECAUTIONARY APPROACH TO THE
REGULATION OF THE MANUFACTURING, MARKETING AND
USE OF CHEMICALS IN EUROPE**

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1. SUMMARY

The Problems with Existing EU Chemicals Legislation

Although the European Community remains one of the largest chemical producing regions of the world, we still know remarkably little about the hazards posed by the vast majority of chemicals currently being manufactured and marketed. In addition to those existing substances which have yet to be assessed, and which, as a consequence, are not subject to regulation, many new substances are manufactured and added to the market each year, again without adequate evaluation of the hazards they may pose.

Current risk-based chemical legislation within the EU, in the form of directives for new and existing chemicals and related instruments, has proved incapable of addressing the scale and severity of the problem. Moreover, such an approach suffers from a number of inherent and fundamental limitations which fatally compromise its utility. Current regulations will never be capable of ensuring an adequate level of protection of the environment and human health from exposure to, and effects of, hazardous chemicals.

For example, since the adoption of Regulation 793/93 on the evaluation and control of the risks of existing substances, five years have been lost in the endless risk assessment of some 110 priority chemicals out of a total of more than 100.000 existing chemicals. Moreover, even for these 110 chemicals, most of which are well known toxins, not a single risk reduction measure has yet been formally proposed within the framework of Regulation 793/93, with yet more institutional barriers waiting for effective implementation of any such recommendation. The current system is failing by design.

The Need for an Alternative, Precautionary Approach

The need for a revision of EU chemicals legislation has already been highlighted in the Informal Environment Council in April 1998 in Chester, England. This became all the more relevant after the Environment Ministers adopted the generational goal at the OSPAR Ministerial Conference in July 1998 in Sintra, Portugal, where they committed to progressively work towards the cessation of discharges, emissions and losses of hazardous substances by the year 2020. A complete structural overhaul of EU chemicals legislation will be essential to achieve the OSPAR objectives, particularly the effective implementation of the generational goal, which needs to be fully transposed into EU legislation.

The Way Forward - Overview of the Alternative Approach

A complete structural overhaul of EU chemicals legislation will be essential in order to meet these challenges. Under the alternative, precautionary approach proposed in this paper:-

chemicals would be *regulated on the basis of their intrinsic properties* (= hazard) instead of on the basis of risk, with special emphasis on persistence and

bioaccumulation

chemicals would be *permitted for use* for limited periods and specific uses instead of just notified

as a *precondition for permission for use*, the following information would be required to be made publicly available:

- within one year of entry into force of new legislation:
 - ~ total production and/or marketed volumes (to be updated yearly)
 - ~ actual applications for >90% of total production/marketed volume (to be updated yearly)
 - ~ the presence of additives or contaminants in the chemicals as produced or marketed

- within three years of entry into force of new legislation:
 - ~ hazard identification and evaluation for high production volume or high market volume chemicals (>1000t/year)

- within five years of entry into force of new legislation:
 - ~ hazard identification and evaluation for remaining chemicals (<1000t/year)

If information was not made available in time, continued manufacture or marketing of the chemicals in question would not be permitted

Immediate adoption of restrictive measures would be required for high production volume or market volume chemicals which are persistent or bioaccumulative or toxic, or which give rise to an equivalent level of concern, with the aim of their substitution with less hazardous alternatives or, preferably, alternatives showing no identified hazard

Phased adoption of restrictive measures would be required for all other hazardous chemicals, again with the aim of their substitution with less hazardous alternatives or, preferably, alternatives showing no identified hazard

*Comparison of the elements of current chemicals legislation
and the changes needed for future legislation*

	Current chemicals legislation	Changes needed for future chemicals legislation
Objective	Risk management of chemicals	Cessation of discharges, emissions and losses of hazardous substances by 2020
Scope	Substances and preparations	Substances, preparations and articles, including intermediates, contaminants, by-products, breakdown products and waste constituents from manufacture, use and disposal
Coverage	< 5% of existing chemicals	100% of chemicals
Basis	Risk	Hazard
Presumption	Chemicals do not pose a risk unless shown otherwise: No data, no restriction (=> ignorance is rewarded)	Chemicals are hazardous unless shown otherwise: No data, no marketing (=> ignorance is punished)
Structure	Incoherent and non-transparent	Coherent and transparent
Confidentiality	Extensive	All data to be made publicly available
Labelling	Substances and preparations	Substances, preparations and goods
Requirements for new chemicals	Notification	Permission for use (time-limited, application-specific); No new hazardous chemicals
Requirements for existing chemicals	Information	Permission for use (time-limited, application-specific); Restrictions on hazardous existing chemicals
Approach	One by one	By groups
Responsibility for assessment	Member States	Independent body
Costs of assessment	Member States	Producer
Restrictions	Marketing and Use	Production, Marketing and Use
Responsibility for restrictive action	Industry Directorate of European Commission	Environment Directorate of European Commission

2. OBJECTIVES AND SCOPE

The following document outlines in more detail the framework for such an alternative approach to the regulation of chemicals in Europe, an approach which is fundamentally more precautionary in nature and which will allow timely and adequate controls on the manufacture and marketing of chemicals, or their release as waste products, in a manner consistent with the need for a high level of protection for human health and the environment.

The ultimate goal of this approach is to achieve an environment free from the current burden of hazardous chemicals. The approach extends the OSPAR objectives for the marine compartment to the environment as a whole, such that the ultimate objective for all environmental compartments, including the human body, should be zero concentrations for synthetic hazardous chemicals and background levels for naturally occurring hazardous substances.

The framework has been developed from the recognition of a number of basic premises:-

that co-ordinated action is essential to protect the environment of the European Community and, furthermore, that the Community has a responsibility to the protection of the global commons;

that continued economic development within the Community should not compromise, or threaten, long-term ecosystem sustainability or the viability of future generations;

that there is an increased awareness within Member States and the Community as a whole as to the significance of environmental protection and the need to avoid problems before they occur, particularly with regard to serious or irreversible degradation of the environment and harm to future generations;

that there is also an increasing awareness of the significance of diffuse sources of chemical exposure, particularly with regard to the chemical constituents of consumer products;

that historic and current practices in the manufacture, use and release of chemicals to the environment have resulted in the presence of, and exposure to, complex mixtures of chemicals, the effects of which will remain very difficult to predict; and

that the Commission and many Member States are already signatory to a number of international agreements designed to address *inter alia* discharges, emissions and losses of hazardous substances to the environment (e.g. North Sea Ministerial Declaration, OSPAR, UNECE POPs Protocol). In particular, the endeavour to move towards the target of cessation of discharges, emissions and losses of hazardous substances by the year 2020, agreed under the OSPAR Convention, will require fundamental revision of current measures to evaluate, permit and control the manufacture, marketing and use of chemicals;

Under the alternative approach proposed, current legislative instruments for the assessment and regulation of both Existing and New Substances would be replaced by a new Framework Directive. This document outlines the principal legislative, financial and administrative provisions which the new Directive would need to incorporate, in order to address:-

- the exchange and availability of information on chemicals;
- the identification of the hazards presented by chemicals as products or constituents of products;
- the substitution of hazardous chemicals;
- the granting of permission to use chemicals for specific applications;
- the labeling of chemicals and chemicals constituents, with particular regard to consumer products;
- the implementation of the precautionary principle and “polluter pays” principle;

These provisions of the new approach would apply to ALL CHEMICALS manufactured, marketed or used in Member States, including:-

- those marketed as substances and as constituents of preparations and articles, and
- those generated as intermediates, contaminants, by-products, breakdown products or constituents of wastes which arise from the manufacture, use or disposal of such products.

This implies that, during the evaluation of a chemical and consideration of appropriate measures, in addition to any intrinsic hazardous properties it may possess, all aspects of the manufacture, use and disposal of that chemical should also be taken into account.

This paper focuses on the changes required to legislation governing the production, marketing and use of chemicals. It does not specifically address the development of the Water Framework Directive. Nevertheless, as the document is intended to provide a general outline of a more responsible and precautionary approach to the manufacture, use and release to the environment of chemicals, as products or wastes, many of the provisions discussed below should be equally applicable within the context of that Framework Directive.

3. GUIDING PRINCIPLES, OBJECTIVES AND MECHANISMS

This new approach to the regulation of chemicals in Europe is intended to be consistent with a number of overarching guiding principles and objectives. Central to this approach is the implementation of the Precautionary Principle (and the principle of preventative action) which is already enshrined within the Treaty [1]. The intention is to provide an outline of mechanisms by which these principles may have practical application.

Guiding Principles

3.1 The **Precautionary Principle** should provide an overarching paradigm to guide decision making even in the absence of certainty regarding the potential impacts of a chemical. This would convey the benefit of any doubt over effects on to the environment accepting that measures may, in some cases, be overprotective in the interests of avoiding harm, especially when uncertainties are large.

In practical terms, the implementation of this principle would imply that:-

action must be taken to avoid harm, or the threat of harm, before it occurs, even when firm evidence of cause-effect relationships is unavailable.

the “burden of proof” is reversed, such that all chemicals are assumed hazardous, and regulated accordingly, until such time as sufficient evidence becomes available that the chemical presents no potential for hazards to ecosystems or human health.

high quality scientific information should form a central component of mechanisms for early detection of threats.

all future technical, social and economic developments implement a progressive reduction in environmental burden.

The last of these points further implies the need for an overall reduction in the use and release of chemicals and, therefore, exposure to them. This would be consistent with the need identified by the European Environment Agency for a reduction in overall chemical load or “intensity” [2].

The principle would thus be implemented in a manner which implicitly incorporates the Principle of Preventative Action, thereby consistent with the Treaty, and which reaffirms the purposes for which the precautionary principle was initially formulated (as the *Vorsorgeprinzip*) [3].

3.2 The **Principle of Sustainability**, such that current exploitation of ecosystem resources, including abstraction of raw materials, consumption of energy, manufacture and use of chemicals and disposal of wastes, does not compromise the viability of future generations and their access to these and other ecosystem services. The development of clean production alternatives (Principle 8) will be

essential in this regard.

As a guide, truly sustainable products and processes may be seen as those which ensure that:-

substances from the Earth's crust do not systematically increase in the ecosphere;
synthetic substances do not systematically increase in the ecosphere;
the bases for productivity and diversity of life are not systematically depleted;
resources are used fairly and efficiently in order to meet human need. [4]

According to points i) and ii) above, it is the systematic accumulation in the environment of substances as a result of human activities *per se* which is undesirable, irrespective of demonstrated or assumed harm. This is in accordance with the OSPAR objective of achieving concentrations in the environment near background values for naturally occurring substances and close to zero for man-made synthetic substances [5,6].

Objectives and Mechanisms

3.3 Zero Discharge, implying the elimination of discharges, emissions and losses of hazardous substances arising from the manufacture, use and disposal of chemicals as substances, or as constituents of preparations or articles. This should apply to all sources of hazardous chemicals, both point and diffuse. Following on from this, as a general principle **consumer products should not contain hazardous substances** as they have the potential to be emitted or lost from those products, resulting in direct exposure of consumers to the chemicals.

Emissions containing substances which are poorly characterised or completely unidentified should be treated as hazardous discharges and targeted for elimination. Where chemicals for which the source is unknown are identified in environmental compartments through research or routine monitoring, every effort should be made to trace the origin of those chemicals such that their release may be addressed at source.

In recognition of the fact that all hazardous chemicals which are discharged, emitted or lost have the potential to reach the marine environment, this will be a necessary step for the implementation of the OSPAR strategy with regard to hazard substances. It would, moreover, extend protective measures to the terrestrial, aerial and freshwater environments and imply a higher level of protection for consumers and for the public in general.

3.4 Consideration of societal need for chemicals, implying that where a chemical is identified as hazardous or where insufficient information exists in order to evaluate hazard, information on applications and use patterns should be used to evaluate the role served by, and the necessity for, that chemical in society. If the hazardous chemical, or problematic process relating to a chemical, is not essential, immediate measures should be required to phase-out that chemical. Ultimately this should lead to the elimination of avoidable exposure to hazardous chemicals.

Where a clear role for society is identified, the obligation must nevertheless remain to replace the hazardous chemical with one which is less hazardous, in accordance with the Principle of Substitution (below).

- 3.5 Implementation of the **Principle of Substitution**, according to which hazardous chemicals must be substituted by less hazardous alternatives or, preferably, alternatives for which no hazards can be identified. The substitution process should not be restricted simply to the substitution of the chemical in question with another chemical, but should also involve consideration of alternative approaches to meeting the defined need, e.g. consideration of alternative products or services to serve the same function in addition to alternative materials for the same product.

Substitution is an iterative process, *i.e.* it does not end simply with the substitution of a hazardous chemical with a less hazardous one but should be an ongoing process of progressive reduction in hazard. The ultimate goal, necessary to fulfil the OSPAR strategy for hazardous substances, is the replacement of hazardous chemicals with those which present no identifiable hazard to man or the environment. Every effort should be made to ensure that this is achieved within one generation (*i.e.* by 2020).

- 3.6 No new hazardous chemicals** should be permitted for manufacture, marketing or use, other than those which may be permitted for a limited period as part of the process of substitution. In the latter instance the commitment remains, nevertheless, to move ultimately to alternatives which present no identifiable hazard.

- 3.7 The development of **Clean Production**, implying continuous replacement of existing systems for manufacture and use of chemicals, and of products in general, with systems which exert progressively lower impacts on the environment and human health and which are progressively more efficient in terms of resource utilization. This in turn implies reduction in the quantities of material, energy and water used, a shift to the use of renewable energy and, wherever possible, renewable raw materials, and enhanced product design to improve durability and to facilitate repair and reuse of components and materials. The ultimate aim is to achieve production processes and, as far as possible, use and disposal patterns which are effectively cyclical, or operate in a “closed loop” configuration.

These guiding principles, objectives and mechanisms would be implicitly observed through the development and implementation of alternative legislative (A), financial (B) and administrative (C) instruments. These are outlined in more detail in the following sections of the document.

A. THE DEVELOPMENT OF LEGISLATIVE INSTRUMENTS

4. PRECAUTIONARY EVALUATION OF CHEMICALS

4.1 Comparison with Existing Instruments

Currently the requirements for regulation of chemicals differ depending on whether they were notified before 1981 (Existing Substances) or after 1981 (New Substances). Assessment of chemicals is risk-based and adopts a substance-by-substance approach.

Of approximately 100 000 Existing chemicals, the vast majority are unassessed, but are effectively presumed non-hazardous and permitted for use until proven otherwise. There is, consequently, little incentive for the provision of additional information on which those assessments can be based.

Of the approximately 2000 New chemicals notified since 1981, assessments are also incomplete. Although the requirements for information prior to notification have been much greater than for Existing substances, many New substances have, nevertheless, been marketed without these requirements being fulfilled.

Although the greater part of the problem undoubtedly lies with Existing chemicals, therefore, current regulation of New chemicals cannot be considered to be adequate.

The proposed alternative approach would effectively replace these existing legislative instruments with one based on **the regulation of chemicals according to hazard**. Chemicals or groups would be subject to an “evaluation” procedure, the central element of which would be a process of **hazard identification** (but which also includes consideration of production volumes, uses, associated wastes, etc.).

Hazard identification is the process by which the intrinsic properties of chemicals or groups (including but not limited to toxicity, persistence and liability to bioaccumulate) are taken into consideration in order to arrive at a description of any and all hazards presented by that chemical or group.

Action would be required to address ALL chemicals identified as hazardous within a restricted timeframe. Information on production volumes and uses would only be used in order to accelerate restrictive measures and substitution for those chemicals which, by virtue of their scale of production or modes of use, present hazards which are particularly widespread and/or direct. Such information must not be used to justify avoidance or delay of action to substitute any particular hazardous chemical within the maximum timeframe for substitution of all hazardous substances.

4.2 Overview of the Alternative Approach

The proposed approach would:-

attempt to unify the evaluation and regulation of all chemicals within Europe, encompassing both New and Existing chemicals, along with the intermediates, contaminants, by-products and degradation products associated with them, in order to ensure that not only the manufacture, marketing and use of all chemicals is properly controlled, but that all discharges, emissions and losses arising from manufacture, use or disposal are also properly addressed.

be based on the regulation of chemicals according to their intrinsic properties, or hazards, and not rely on the prediction of exposure and the calculation, assessment and management of risks.

consider persistence to be an indication of the potential for long-term and widespread contamination of, and possibly impacts on, environmental compartments, and therefore as a key criterion in the hazard identification process.

presume that chemicals are hazardous until demonstrated otherwise, *i.e.* until hazard identification is completed, or in those instances where hazard identification is limited by lack of information, chemicals must be assumed to present hazards of unknown proportions.

The adoption of a hazard-based approach in place of the current risk-based approach is a necessary step, in recognition of the substantial and, to a large degree, inherent limitations in the identification of exposure pathways and the accurate quantification of exposure to chemicals. This alternative approach accepts that exposure of one or more ecosystem compartments to a chemical will be a possible and, in many cases, likely, consequence of the manufacture, use or disposal of that chemical.

As noted above, it is intended that the approach should lead ultimately to the substitution of all hazardous substances, irrespective of use patterns. However, given the potential for direct or widespread exposure, chemicals used in open applications, and in consumer products in particular, or which are released to the environment in waste streams, should be given priority. Nevertheless, it must be recognised that even for chemicals used in “closed” applications, the potential exists for release to the wider environment (*e.g.* through catastrophic accidental releases or through contamination of products with process chemicals). Accepting that no process is entirely closed, substitution should, ultimately, also address these chemicals.

4.3 Steps in the Evaluation of Chemicals

The process would adopt a step-wise approach designed:-

- 4.3.1 to reduce the overall number of chemicals which require evaluation by excluding those existing substances which are no longer manufactured, marketed or used in the Community;
- 4.3.2 to organise the remaining chemicals wherever possible into groups on the basis of similarity in chemical structure, presence of active groups or chemical properties, such that the need for evaluation on a substance-by-substance basis may be minimised;

- 4.3.3 to collate existing information from a wide range of validated sources, or obtain new information (within a limited timeframe), on the basis of which the hazards presented by chemicals or groups can be identified;
- 4.3.4 to evaluate chemicals or groups in a precautionary manner, leading to a decision either:-
- to substitute the chemicals, if hazardous, within a specified and limited timeframe, along with the introduction of interim measures to restrict applications and control discharges, emissions and losses as far as possible
 - or
 - to permit the continued use of chemicals for which no hazard is identified for defined applications and for a specified period, after which the permitted uses should be re-evaluated. Earlier re-evaluation of permitted chemicals may be necessary in light of new information of relevance becoming available.
- 4.3.5 to allow consideration of use patterns and the role served by the chemicals in question within society in order to guide the timing of substitution and the need to introduce other restrictive measures in the interim.

These stages are elaborated in more detail below.

In practice, stages 4.3.3 and 4.3.4 may be expected to proceed in parallel, *i.e.* evaluation of some chemicals should be possible at the same time as the collation of information is ongoing for other chemicals.

Furthermore, the process of grouping of chemicals (stage 4.3.2) should not be seen as a precondition to further evaluation, but as a mechanism by which chemicals may, wherever possible, be evaluated and regulated by group in order to increase efficiency and allow more simple, effective and timely regulation.

Chemicals or groups for which evaluation is not possible, due to poor availability of information, would be considered to present unknown hazardous, classified as **unevaluated** and targeted for substitution accordingly.

Note: Existing vs New Substances

Given the magnitude of the problem relating to Existing substances, priority may need to be given to these chemicals for evaluation and regulation. Nevertheless, recognising that by no means all New substances have undergone the assessments required even according to current legislation and, moreover, that the regulation of chemicals under the alternative approach proposed here is yet more stringent than current provisions for New substances, the proposed alternative approach to evaluation would ultimately need to encompass New substances as well.

4.3.1 Pledge of Interest in the Manufacture or Marketing of Chemicals

Although the list of Existing Substances (EINECS) contains 100 106 entries, it is suspected that only between 20 000 and 70 000 are currently manufactured or marketed within the Community [2]. In order to avoid wasteful evaluation of chemicals which are no longer in use, Industry would initially be requested to pledge support for those chemicals for which they wish to retain an interest in manufacturing, marketing and/or using.

This pledge would need to be received within 1 year of the new legislative framework entering into force, together with data on production volumes, by-products and downstream uses. Any chemicals for which a pledge is not received within this timeframe would no longer be permitted for use with immediate effect. Subsequent applications to manufacture or market these chemicals would entail comprehensive evaluation, with no permission granted until such evaluation is complete and favourable.

Information on production processes and volumes, upstream and downstream uses and disposal considerations, in addition to any information relating to the distribution and abundance of the chemical or group in question, would be required. Data on total production volumes and on downstream applications for greater than 90% of this production volume should be collated for all pledged chemicals within one year of entry into force of the legislation. This information should subsequently be updated on an annual basis.

It is essential that provisions for commercial confidentiality do not prevent the timely and proper evaluation of chemicals. Making the provision of information on production volumes and applications a requirement for continued production, marketing or use to be considered should help to ensure that this does not occur.

Pledging interest in a chemical would imply the acceptance by Industry of the financial responsibility to ensure that sufficient information is available adequately to identify all possible hazards presented by a chemical.

The assumption that all New Substances currently remain in production should be confirmed through the same process. Thereafter, those New substances for which pledges were received would be subject to evaluation in the same manner.

4.3.2 Assignment of Chemicals to Groups

In order to accelerate the hazard identification of the pledged substances, and to facilitate the regulation of those which are currently non-assessed, chemicals would be arranged in groups according to chemical structure, possession of particular active groups or chemical properties.

Although a universal mechanism for such grouping remains to be developed, it must be recognised that this approach is by no means new. Many international conventions are designed to regulate chemicals by group rather than strictly on a substance-by-substance basis; for example, the OSPAR list of chemicals for priority action [6] principally consists of chemical groups.

The process of grouping of chemicals should not form a barrier to further evaluation and effective implementation of necessary measures. In other words, where it is not possible to place a particular chemical in any one group, hazard identification must proceed for that chemical individually if sufficient information regarding properties is available. While intended as a mechanism to increase the efficiency with which chemicals can be evaluated and regulated, grouping is not, therefore, a precondition to further evaluation.

4.3.3 Collation of Information for Hazard Identification

In order to conduct the hazard identification for each chemical or group, data should be collated regarding all aspects of toxicity, persistence and capacity to bioaccumulate for the chemical or group in question. A total of three years (for high production volume chemicals, *i.e.* >1000 tonnes/y) or five years (for other chemicals) would be permitted for the collation of all other data necessary for hazard identification to proceed, unless a decision that a chemical or group is hazardous can be made on the basis of more limited information.

The hazards associated with intermediates, by-products, contaminants and degradation products of manufactured and marketed chemicals should also be taken into account as part of the process. For chemicals marketed as components of mixtures (preparations or articles), the potential for hazards to arise as a result of physico-chemical interactions between components should also be subject to consideration.

In order that the hazard identification process be as informed as possible, information from all available sources should be collated. For example, an updated list of chemicals for which information is sought could be circulated to Universities, research institutes, industry and other relevant organizations, and made available on the Internet, so that individuals or organizations may submit information which they feel to be relevant for consideration. The quality of all data or other information submitted would, of course, need to be considered as part of the evaluation. The interpretation of higher quality data or information would be given the greater weight.

Hazard identification may proceed as soon as sufficient information is available. In other words, in instances where it is clear from a more limited subset of data that the chemical or group presents significant hazards, further collation of data may be unnecessary in order for evaluation and regulation to proceed.

In contrast, if all available data collated are inadequate to allow evaluation, particularly with regard to persistence, toxicity, bioaccumulation, production volumes, by-products and uses, the chemical or group would be temporarily classified as **unevaluated**. Further information on which to base an evaluation could then be

obtained through primary research or routine testing procedures within the period remaining (*i.e.* the 3-5 years, depending on production volume). This research or testing should be conducted as far as possible by independent institutions, financed by those sectors of Industry which have an interest in continuing to manufacture or market the chemical in question.

If, at the end of these prescribed periods (3-5 years), the information available remains inadequate, the chemical or group should remain classified as **unevaluated** and would not be permitted for continued use.

4.3.4 Hazard Identification Process

The process by which chemicals are subject to hazard identification should be precautionary both in nature and intent. This implies the consideration, wherever necessary, of all available data and information relating to a chemical, arising both from screening, monitoring or testing of substances and from primary research, in a less prescriptive manner than classical assessment procedures.

The potential for complex interactions between chemicals present as mixtures, *e.g.* in products or wastes, and consequent impacts on persistence, toxicity and capacity to bioaccumulate, should also be taken into account.

The less prescriptive nature of precautionary hazard identification should not be viewed as disadvantageous in this regard, but rather as a mechanism which enables all relevant data and accumulated scientific knowledge relating to the properties of a chemical to form part of the evaluation procedure as necessary.

All hazard identifications should be conducted by independent institutions in a transparent manner and be subject to independent comment and review as well as periodic random auditing. Finance for the evaluation would be provided by a European Chemicals Fund, administered by the European Chemicals Bureau (see discussion of financial instruments in section B below).

The process of hazard identification may be based in part upon comparison against a range of set points for certain standardised testing procedures, *i.e.* cut-off criteria, but should not be restricted to such simplistic evaluation schemes.

Rather it is essential that properties such as toxicity, persistence and capacity to bioaccumulate are viewed as complex and continuous properties and that all information which is available and useful should be taken into account when reaching a precautionary decision, unless the hazards of a chemical can be clearly identified on the basis of a more limited subset.

As far as possible, uncertainties surrounding measurements and estimates should be made explicit, at least in qualitative terms, and, wherever possible, the magnitude of such uncertainties taken into account in the hazard identification process.

The hazard identification process would, of course, be designed specifically to identify those substances which are hazardous. The process may, therefore, **ONLY**

result in the classification of chemicals as **hazardous, unevaluated** or as not meeting the criteria for either of these classifications *i.e.* demonstrating no identified hazard. Failure to identify hazardous properties for a particular chemical cannot be used to guarantee the safety of that chemical under all circumstances. Such chemicals may be permitted for continued use within specified applications, but may not be classified as “non-hazardous” as the hazard identification process cannot demonstrate that any chemical is entirely safe.

In circumstances in which a single chemical is classified as hazardous as a result of evaluation, chemicals of the same group (*i.e.* with similar structures, active groups, etc.) which have yet to be evaluated should then be assigned the same classification as the evaluated chemical. In cases in which a number of chemicals from that group have been evaluated, those from that group which are still awaiting evaluation may only be assigned the same classification as the most hazardous member of that group.

In the process of grouping chemicals for evaluation, evidence that any member or members of a particular group do not show hazardous properties should not be used to support the assumption that all chemicals in the group, including those still awaiting evaluation, will similarly not show hazardous properties.

Substances for which, for what ever reason, grouping and group evaluation was not possible, and which could not be evaluated as single chemicals due to poor information availability, would remain classified as unevaluated, pending provision of further information. Should the data on which to evaluate the chemical not be forthcoming within the 3-5 year period, immediate substitution of that chemical would be required.

4.3.5 Consideration of Societal Need

Whenever a chemical is found to be hazardous, consideration should also be given to the role served by that chemical within society as, where this role is determined to be non-essential, it may be possible to phase out the chemical more rapidly without the need to identify a substitute.

4.4 Principal Criteria for the Identification of Hazardous Substances

A substance should be considered hazardous if it is found to possess any **one or more** of the three properties of **persistence, toxicity or ability to bioaccumulate**, or if the information available indicates the need for an equivalent level of concern, *e.g.* if the chemical is reported to be present in remote regions or at high concentrations in biological tissues. Substances which may be found in the environment but which cannot be reliably identified must be assumed to be hazardous until identified and demonstrated otherwise.

4.4.1 Persistence

Persistence should be seen as a key hazard criterion of the evaluation as it is a strong indication of the potential for the chemical to present long-term hazards when released to the environment. In this way, it is the accumulation of persistent chemicals in the environment as a result of human activities which is viewed, in itself, to be undesirable, without the requirement for the existence of demonstrable biological impacts. Although numerical criteria for persistence still need to be developed, when a chemical is identified as persistent, it should be targeted for substitution with more readily degradable alternatives.

Substances which are less persistent, but for which exposure may be expected to be continuous and elevated as a result of continued widespread release (*e.g.* volatile or leachable components of consumer products), may give rise to an equivalent level of concern and require similar action to eliminate emissions and losses.

Persistence should, as far as possible, not simply be evaluated on the basis of inherent or ready biodegradability. Standardised tests for biodegradability routinely involve monitoring of degradation rate under conditions of enhanced nutrient status and bacterial activity which may yield rates representative only of the very highest rates which may be expected in the field. It is essential, therefore, to take into account the potential for degradation and, conversely, persistence under non-ideal conditions. Consideration should also be given to the rates of chemical and photochemical degradation in the absence of biological activity.

Environmental persistence should not be confused with product durability. Durable products are, clearly, essential and components of such products must be expected not to break down under normal conditions of use. Such products and components should, as far as possible, be marketed in a closed loop system, such that those marketing the product operate a “take-back” policy and, as a consequence, retain ownership of, and responsibility for, the components of concern. Ultimately, materials used for durable products should be amenable to biodegradation under certain specific conditions, such that they would not present a persistent problem following final disposal.

4.4.2 Toxicity

Toxicity should be considered to include all aspects of acute and chronic impacts, including the potential for transgenerational effects. This includes, for example, the initiation or promotion of cancer, induction of birth defects or genetic damage, interference with the endocrine system or other chemical signalling mechanisms, damage to nervous or immune systems, irritation of skin or other membranes or induction of allergies or sensitivities to other chemicals. The potential for modification of toxicity resulting from interactions with other components of chemical mixtures (*e.g.* in products or wastes) should also be taken into account.

Direct evidence of health effects in whole organisms should not be an absolute requirement before action is considered necessary. Reproducible data from *in vitro* studies may, in some instances, be considered sufficient basis for the development of restrictive measures. This is particularly important in relation to the potential for substances to interfere with the endocrine system, for which current understanding of *in vivo* processes, and the development of sensitive whole-organism assays remains relatively poor. Dose-response relationships are also unclear, but appear in some instances to depart from classical models.

Reliable and reproducible evidence that a chemical is capable of interacting with hormone, or other endogenous chemical communication, systems at a fundamental level should be sufficient grounds for that chemical to be targeted for substitution.

4.4.3 Bioaccumulation

Capacity to bioaccumulate, like persistence, may be considered alone to represent a significant hazard criterion as it provides a mechanism by which chemicals may concentrate to substantially higher levels in biological systems than are present in abiotic environmental compartments. It is not essential for a chemical to be persistent or demonstrably toxic in order for its bioaccumulative potential to be of concern. As noted above, chemicals which are less persistent but for which environmental levels are sustained by continuous production and releases may still have the potential to accumulate. Again, substitution with less hazardous alternatives would be required.

4.5 Reference to Existing Lists of Hazardous Substances

A number of lists of chemicals and groups already identified as hazardous and, therefore, targeted for restrictive measures exist within certain international agreements, to which numerous Member States and the Commission itself are signatory. These lists should be taken into account in order to avoid needless re-evaluation of substances already well known to be hazardous and to guide priority action for these substances.

The OSPAR List of Chemicals for Priority Action (Annex 2 of the OSPAR Strategy with Regard to Hazardous Substances) [6] provide a practical example of the application of the group evaluation approach. They also represent groups of chemicals for which further evaluation simply will not be necessary prior to taking action. These groups are recognised as hazardous and action to substitute these is a requirement for the implementation of the OSPAR Strategy, as agreed by the

Commission and most Member States[5,6].

Similarly, action is already required to address a number of persistent organic pollutants (POPs), all organohalogenes, under the UNECE LRTAP Convention POPs Protocol. These chemicals are particularly problematic as they are not only persistent but also highly toxic and bioaccumulative with a tendency to be carried over long distances by air currents before deposition. The Commission and Member States must recognise the urgency of the development, implementation and enforcement of measures to substitute this particularly hazardous group of chemicals and must act to ensure effective legislation in this regard. Furthermore, the Community should play a leading role in the ongoing development of the UNEP global POPs Convention.

5. CONSEQUENCES OF EVALUATION

As noted above, hazard identification may lead to classification of a chemical as **hazardous, unevaluated** or as not meeting criteria for either of these, *i.e.* demonstrating no identified hazard. Consideration of this classification, together with information on production volumes, uses etc., would then guide the nature and timing (respectively) of action required.

5.1 Hazardous Chemicals

All hazardous chemicals should be targeted for substitution (or elimination for those identified as non-essential), irrespective of production volume or use patterns.

Substitution should take place within a specified, limited period, *e.g.* 5 years from the date on which evaluation was completed. Where chemicals are classified as hazardous on a group basis, substitution would be required for all members of that group.

For high production volume chemicals (HPVC) or chemical constituents of consumer products identified as hazardous, more immediate substitution (*e.g.* within 3 years) should be required, in recognition of the greater potential for widespread or excessive exposure to these chemicals and the hazards they present.

Where hazard identification yields an indication of extreme hazard according to any one criterion (persistence, toxicity or bioaccumulative capacity), or demonstrates that a chemical possesses two or more of these hazardous properties, immediate measures (*i.e.* an emergency ban) should also be emplaced to prevent the marketing or use of that chemical in consumer products and other open applications. In the case of toxicity, such an approach would be similar to that for substances with the potential to cause irreversible damage (specifically carcinogens, mutagens and reproductive toxicants) under Directive 76/769 [7], *i.e.* that these would not be permitted for marketing to or use by the general public, with immediate effect.

On this basis, immediate restrictions should be a requirement for those specific chemicals and groups on the OSPAR List of Chemicals for Priority Action (Annex 2 of the OSPAR Strategy with Regard to Hazardous Substances) [6].

Any such immediate measures would be emplaced in addition to, and not instead of, the requirement for substitution of the hazardous chemical from all applications within the fixed period.

Substitution must be conducted in a manner consistent with the guiding Principle of Substitution, elaborated further below (Section 6). All current applications of the substance must be addressed.

Financial incentives should be used in order to encourage earlier substitution (*i.e.* before the *e.g.* 5 year deadline) where possible, with financial (and possibly legal) penalties imposed should the chemical not be substituted within the agreed period. Financial provisions are discussed in greater detail below (Section 8).

As noted above, where the role served by a hazardous chemical is determined to be non-essential, it should be possible simply to phase out the chemical without the need to identify a substitute. Early phase-out of such chemicals (*i.e.* as early as possible within the *e.g.* 3-5 year period) should be encouraged. Addressing these chemicals or groups should reduce overall avoidable exposure to hazardous chemicals.

5.2 Unevaluated Chemicals

Chemicals which are temporarily classified as **unevaluated** (*i.e.* those for which insufficient data exist for evaluation but for which time for collection and collation of information is still available) should be assumed to possess unknown hazards and regulated accordingly. Action should be taken to minimise as far as possible discharges, emissions and losses of such chemicals while the process of data gathering is ongoing. The chemical in question, and all preparations and articles containing that chemical, should be labelled to indicate the presence of an unquantified hazard; the need for appropriate labelling is expanded further below.

If sufficient data to allow evaluation are not forthcoming within the specified period (*i.e.* 3 years from entry into force of the legislation for HPV chemicals, 5 years for others), the chemical should remain classified as **unevaluated**. Such chemicals would not be permitted for continued use in any applications, with immediate effect. Any subsequent interest in the manufacturing or marketing of the chemical would entail re-notification as a new chemical and, therefore, be subject to comprehensive and favourable evaluation prior to any uses being permitted.

Unevaluated chemicals should only be substituted by chemicals for which the hazards are known and which represent the least-hazardous alternative currently available for each application.

5.3 Chemicals Demonstrating No Identified Hazard

Chemicals or groups for which sufficient information was available to enable evaluation, but for which no hazards were identified, would be permitted for continued use in the applications specified during the evaluation process. Permission

to use these chemicals would be subject to periodic review (every 5 years).

Earlier review may be justified in instances in which new or additional information of substance becomes available. Such information may be submitted and a review requested by any individual or organization. However, the necessity for such a review should be judged on the basis of the strength and significance of the new or additional information provided. Whenever review is not judged to be necessary, the basis for this judgement will be made public (*e.g. via* the Internet).

6. EVALUATION OF POTENTIAL ALTERNATIVES

Whenever the need for substitution of a chemical is established, the evaluation of alternatives should be conducted by comparison against a set of ideal criteria rather than simply against each other. These criteria should be based upon the necessary criteria for clean production, bearing in mind also the guiding principle of sustainability.

In other words, evaluation of alternatives would not proceed by simple comparative assessment of alternatives but rather by parallel evaluation of each of the alternatives against a set of ideal criteria. This principle would help ensure that the process of substitution was seen as an iterative process which did not stop as soon as a less-hazardous alternative was available but, instead, encouraged progressive replacement with substances of lower hazard.

In cases in which none of the alternatives presented meet or approach the ideal criteria, the option remains to accept neither the original chemical nor any of the alternatives presented and to seek additional alternative products or approaches which may more closely approach the criteria. Alternatively, particularly where a chemical serves an essential role in society, the best alternative currently available may be selected as an interim measure.

However, this does not necessarily imply the end of the substitution process. Where alternatives arise which more closely approach the criteria, further substitution may be required, consistent with the principle of precautionary action and the need for progressive development of clean production processes. Every effort should be made to ensure the replacement of all hazardous substances with alternatives which show no identified hazard within one generation (*i.e.* by 2020). Such an approach would help to ensure the effective implementation of the OSPAR Ministerial agreement.

As noted above, substitution should not be limited simply to the replacement of one substance or material with another, but should include some consideration of alternative products to serve the same function and alternative approaches to meet the need for which the original chemical was manufactured and marketed.

In order to increase to efficiency with which substitutions are made, the potential for the “clustering” of chemicals or groups according to application or chemical industry sector should be explored. “Clustering” would not imply that all the chemicals to be addressed possessed similar properties or hazards but would simply encourage coordinated action to address specific industrial processes or fields of product

application.

7. LIABILITY

The responsibility of those manufacturing or marketing a hazardous chemical for the presence and effects of that chemical in the environment should not end with the process of substitution. The moral and financial responsibility for measures to prevent further releases to the environment and to remediate existing damage should remain with the originators. Moreover, arrangements should be made by the company marketing the chemicals of concern to enable and encourage return of any obsolete or otherwise unused products to the company, such that the responsibility for appropriate disposal rests with the original marketer.

B. THE DEVELOPMENT OF FINANCIAL INSTRUMENTS

8. FINANCIAL INCENTIVES AND PENALTIES

The “polluter pays” principle is also enshrined within the Treaty. However, in order to be consistent with the legislative provisions of the proposed approach, it is essential that this principle be implemented in a manner which:-

supports progressive development of clean production alternatives,

imposes penalties when the requirements of the substitution process are not met, and

provides funds for independent evaluation of chemicals,

and NOT in a manner which:-

allows continued discharge, emission or loss of hazardous substances providing those responsible can pay.

To this end, fees or fines paid by those manufacturing or marketing chemicals must remain secondary to action required to substitute hazardous chemicals *i.e.* financial incentives or penalties may encourage substitution earlier than the required deadline but should not allow a delay in substitution beyond this deadline.

Under the proposed alternative approach, the “polluter pays” principle would be implemented in the form of both “producer/marketer pays” fees and “polluter pays” fines.

8.1 Fees

For all chemicals manufactured or marketed within the Community, a fee would be payable to a European Chemicals Fund, administrated through the European Chemicals Bureau. The fees would be set centrally within the European Commission, and based on production volume of the chemical and on the extent of hazard posed.

The fee payable for manufacture or marketing of chemicals which are neither evaluated as hazardous, nor remain unevaluated would be relatively small and dependent principally on production volume in the form of a tax.

Fees payable for hazardous chemicals, for which continued use was permitted for a specified period, would be significantly higher in order to act as an incentive to encourage substitution with non-hazardous alternatives as rapidly as possible. Fines would be emplaced if the conditions of use are not observed or if the chemical is used for application other than those specified during the permitting process.

Commitment from the manufacturer or marketer of the chemical in question to measures leading to substitution of the chemical could be rewarded by temporary

reduction in the fee payable, providing such commitment is supported by a credible strategy and that it can be demonstrated at any time during the waiver period that the processes leading to substitution are ongoing. Similarly, positive financial assistance may be provided to assist companies in the development of innovative alternatives.

8.2 Fines

Failure to meet the target of substitution within the period over which the hazardous chemical was permitted for continued use would result in substantial increase in the size of the fee charged. Manufacturers or distributors would be liable to pay substantial periodic fines should the agreed substitution continue not to be implemented over time. In cases in which violation of the principle of substitution continues for 1 year or more beyond the date initially agreed as the deadline for substitution, legal action may be necessary in order to prevent continued manufacture, marketing and use of the chemical in question.

8.3 Administration of funds

All monies raised through the charging of fees and fines would be administered through the European Chemicals Fund and used for five principal purposes:-

- to fund further screening, monitoring and evaluation of chemicals and primary research;
- to permit post-marketing surveillance of chemicals in order to evaluate the accuracy of specified use, performance and disposal patterns;
- to provide with financial incentives, or assist with capital expenditure, those companies or sectors of the chemical manufacturing and processing industries which are developing clean production alternatives;
- to fund a European Clean Production Programme which would promote clean Production through research, education and provision of information;
- to fund the administration systems required in order to oversee and manage the implementation of the proposed changes to the regulatory systems.

C. OTHER ADMINISTRATIVE DEVELOPMENTS

9. REQUIREMENTS FOR IMPROVED LABELING

All chemicals marketed or used as substances or as constituents of preparations or articles must be accompanied by labeling indicating any and all hazards which might be relevant and specifying precisely the permitted applications and appropriate storage, handling and disposal instructions. The label "Harmful to the Environment" must be used wherever appropriate on both existing and new chemicals.

Labeling is particularly important in relation to consumer goods, particularly where they consist of or contain hazardous constituents or unevaluated chemicals, permitted for continued use for a defined period prior to substitution. Those substances, preparations or articles comprising or containing the hazardous or unevaluated constituents must be labeled with detailed information regarding contents, hazards and appropriate measures for safe handling, storage and disposal. Whenever one or more constituents of a product are classified as Unevaluated, the labeling should reflect this and advise a high level of caution when handling.

10. AVAILABILITY OF INFORMATION

All chemicals marketed as substances or as constituents of preparations or articles within the European Community should be entered on a European Product Register, along with information on producers, production volumes, hazards and required labeling, status of evaluation and classification according to the scheme outlined above (including any timeframes for substitution), permitted applications and current use patterns. This register would be openly accessible to the public free of charge (*e.g. via* the Internet) and would be maintained and administrated through the European Chemicals Bureau and funded by the European Chemicals Fund.

In addition, all data submitted as part of the evaluation process, along with any documentation relating to the evaluation and classification of each chemical or group and a short statement in support of that classification, will also be publicly available, free of charge.

11. REFERENCES

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